

during a user's exhalation, the flow of gases from said first opening is directed to said first auxiliary outlet.

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B4/ 12. (Once Amended) A system as claimed in claim 10 wherein said valve means of said device comprises an axially moveable member including means for substantially sealing inside said body portion, said member in use axially moveable within said body portion.

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#### **REMARKS**

Applicant, by the amendments presented above, has made a concerted effort to present claims which more clearly define over the prior art of record, and thus to place this case in condition for allowance. Currently, claims 1-21 are pending.

#### ***Allowable Subject Matter***

The Examiner indicated that claims 4-7 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Examiner indicated that claims 14-21 would be allowable if rewritten to overcome the rejection under 35 U.S.C. §112, second paragraph, set forth in the Office Action and to include all of the limitations of the base claim and any intervening claims.

The Examiner has withdrawn the allowability of claims 1-3.

***Claim Rejections - 35 U.S.C. §112***

Claims 3 and 8-21 were rejected under 35 U.S.C. §112, second paragraph. Applicant has amended claims 3, 8 and 12 to overcome the Examiner's rejections. Reconsideration and allowance of claims 3 and 8-21 is respectfully requested.

***Claim Rejections – 35 U.S.C. §101***

Claims 8-21 were rejected under 35 U.S.C. §101. Claim 8 has been amended such that the positive recitation of the gases delivery means being in communication with the user has been deleted. Reconsideration and allowance of claims 8-21 is respectfully requested.

***Claim Rejections – 35 U.S.C. §102(b)***

Claims 1-3, 8, 10 and 12 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by United States Patent No. 4,088,131 to Elam. Reconsideration and allowance of the claims is respectfully requested in view of the amendments and remarks herein.

Independent claim 1 has been amended to specify a spontaneously breathing user. Independent claim 8 requires modes of operation during inhalation and exhalation of the user.

Elam does not disclose a device for use with a spontaneously breathing patient. Thus, the requirements of claims 1 and 8 including modes of operation during inhalation and exhalation are not pertinent to the disclosure of Elam. Applicant submits that it is clear that the device of Elam would not be practical to employ in a situation where the patient is spontaneously breathing. During exhalation of the patient, claim 1 requires that gases flow from the pressurized gas source to be vented externally and claim 8 requires that the flow of gases from the first opening are directed to the first auxiliary outlet. In Col. 4 of Elam, the second phase of operation is such that valve 52 is closed. Thus, during spontaneous

exhalation of the patient, Elam does not disclose the flow of gases from the pressurized gas supply to be vented externally through an outlet.

Applicant submits that it is also unclear what would occur in Elam during spontaneous inhalation. Claim 1 requires the pressurized air to be delivered to the patient during inhalation to achieve the desired positive airway pressure and claim 8 requires that the flow of gases from the first opening is directed to the second opening. If the flow of oxygen has not been selected, Applicant submits that it is possible that the patient would suffocate if the bag was not compressed. If oxygen were selected during phase three, it is free to flow out through port 30. Thus, the benefit of CPAP treatment would be lost because the positive pressure could not be maintained. Applicant submits that it is clear from the disclosure of Elam that the device would not work in the case of a spontaneously breathing patient and, therefore, that the two modes of operation required by claims 1 and 8 during exhalation and inhalation of a spontaneously breathing user would not be met. Accordingly, Applicant submits that claims 1 and 8 are not anticipated by and are not rendered obvious by Elam. Reconsideration and allowance of claims 1 and 8 is respectfully requested.

Claims 2 and 3 are dependent upon claim 1 which Applicant submits is in condition for allowance. Reconsideration and allowance of claims 2 and 3 is respectfully requested.

Claims 10 and 12 are dependent upon claim 8 which Applicant submits is in condition for allowance. Reconsideration and allowance of claims 10 and 12 is respectfully requested.

***Claim Rejections – 35 U.S.C. §103***

Claims 9, 11 and 13 were rejected under 35 U.S.C. §103 as being unpatentable over Elam.

Claims 9, 11 and 13 are dependent upon claim 8 which Applicant submits is in condition for allowance. Reconsideration and allowance of claims 9, 11 and 13 is respectfully requested.

Moreover, claims 9, 11 and 13 require humidifying the gases before delivery to the user. Elam does not suggest using humidified gases. If humidified gases were introduced to bag 13 in Elam, it is likely that condensation would occur resulting in welling of water and possible malfunction of the device. Also, during the second phase of operation described in column 4 of Elam, Applicant submits that it is not apparent if the user was inhaling during this period how such humidified gases would be delivered. Accordingly, Applicant submits that claims 9, 11 and 13 are not rendered obvious by Elam. Reconsideration and allowance is respectfully requested.

A version of any amended claims, on separate pages from the amendment, marked up to show all the changes relative to the previous version of the claims (underlining or bracketing) is also provided herewith in conformance with 37 C.F.R. 1.121(c)(1)(ii).

A clean version (no underlining and bracketing) of the entire set of pending claims, on separate pages from the amendment, is also provided herewith as detailed in 37 C.F.R. 1.121(c)(3).

In view of the above Amendments and Remarks, Applicant respectfully submits that the claims of the application are allowable over the rejections of the Examiner. Should the Examiner have any questions regarding this Amendment, the Examiner is invited to contact one of the undersigned attorneys at (312) 704-1890.

Respectfully submitted,

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**MARKED UP VERSION OF AMENDED CLAIMS IN  
CONFORMANCE WITH 37 C.F.R. 1.121(c)(1)(ii)**

1. (Twice Amended) A device for controlling the gas flow between a pressurised gases supply and a spontaneously breathing user, comprising:
  - a body portion including a first opening adapted to be in fluid communication with a pressurised gases supply, a second opening adapted to be in fluid communication with a user, a first auxiliary outlet in said body portion, and
  - valve means adapted such that during a user's inhalation, the flow of gases from said first opening is directed to said second opening, and during a user's exhalation, the flow of gases from said first opening is directed to said first auxiliary outlet.
  
3. (Twice Amended) A device as claimed in claim 2 wherein said valve means comprises an axially moveable member [of a construction suitable to] including means for substantially [seal] sealing inside said body portion, [but] said member in use axially moveable [therein] within said body portion.
  
8. (Twice Amended) A system for supplying gases to a user at a pressure above ambient comprising:
  - a pressurised gases supply,
  - gases delivery means for supplying said gases to [said] a user, said gases delivery means being in fluid communication with said pressurised gases supply [and said user], and
  - flow control means disposed within said gases delivery means or in fluid communication therewith, said flow control means comprising a device for controlling the gas flow [between a pressurised gases supply and a user] within said gases delivery means, said device including a body portion including a first opening adapted to be in fluid communication with [a] said pressurised gases supply, a second opening [adapted to be in] for providing fluid [communication with a user] flow to and/or from said flow control means, a first auxiliary outlet in said body portion, and valve means adapted such that during a user's inhalation, the flow of gases from said first opening is directed to said second opening, and during a user's exhalation, the flow of gases from said first opening is directed to said first auxiliary outlet.

12. (Once Amended) A system as claimed in claim 10 wherein said valve means of said device comprises an axially moveable member [of a construction suitable to] including means for substantially [seal] sealing inside said body portion, [but] said member in use axially moveable [therein] within said body portion.